

Appl. No.: 10/786,636
Amendment dated November 28, 2005
Reply to Office Action of August 26, 2005

REMARKS/ARGUMENTS

Reexamination and reconsideration of the Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the remarks that follow. Claims 1, 10, 14, 16, and 20 have been amended to incorporate the subject matter of claims 2, 11, 15, 17, and 21, respectively. Claims 2, 11, 15, 17, 21, and 24-26 have been cancelled. No new matter is introduced by these amendments. Applicants respectfully submit that these amendments place the application in condition for allowance or, at the very least, place the claims in better form for appeal. For these reasons, Applicants respectfully request entry of this amendment. Claims 1, 3-10, 12, 14, 16, 18, 20, and 22 are pending in the application.

Claims 1-10, 14-18, and 20-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,468,514 in view of any one of Chemical Abstracts XP 002233114; XP 002233115; or XP 002233116. The Office argues the '514 patent teaches the use of surfactants, such as sodium lauryl sulfate (SLS), in personal hygiene and further teaches combining different types of surfactants to replace SLS with milder surfactants. The Office also argues the XP references teach olive oil carboxylate as a natural and mild cleansing surfactant and that it would be obvious to combine the references to arrive at the present invention. Applicant respectfully traverses this rejection.

The '514 patent discloses that the addition of N-acyl amino acid co-surfactants to lauryl ether sulfate leads to a reduction in the amount of lauryl ether sulfate adsorbed on skin. The XP abstracts merely disclose that skin cleansing agents can be derived from olive oil. The Office argues a skilled artisan would be motivated to combine the references because they form analogous art, "addressing the same problem in the same field of endeavor." Further, the Office argues the combination would be made with an "expectation to achieve a synergistic cleansing effect" and "reduce the irritation of SLS by adding other surfactants, which have cleansing power." Applicant respectfully disagrees and suggests that in making the combination of the references, the Office is characterizing the references in a manner that does not reflect what the references fairly teach or suggest.

MPEP 2141.02 states a "prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." Applicant

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respectfully submits the Office is improperly broadening the disclosure of the '514 patent by failing to recognize the underlying theory on which the disclosure is based. Accordingly, the Office is creating a motivation to combine the references where none is present.

First, Applicant respectfully points out that the '514 patent discloses a specific combination of specific co-surfactants for a specific purpose. The '514 patent discloses that sodium lauryl ether sulfate binds to the surface of the skin where it forms a certain reservoir (column 1, lines 65-67). It further discloses that the person skilled in the art who would like to increase the skin compatibility of surfactant combinations including sodium lauryl ether sulfate replaces some of the sodium lauryl ether sulfate with milder surfactants, which has the adverse effect of reducing foaming and/or cleansing performance (column 2, lines 42-47). To remedy this shortcoming, the '514 patent sets out to achieve a specific goal, that being to provide a composition based on sodium lauryl ether sulfate as the cleansing surfactant wherein the amount of sodium lauryl ether sulfate adsorbed on the skin is reduced through addition of a co-surfactant (column 4, lines 40-43). The compositions disclosed by the '514 patent arise from this specific goal (*i.e.*, reduced SLS skin binding), and the suggestion or motivation provided by the '514 patent can not be separated from this goal.

To achieve the stated goal, the '514 patent discloses that N-acylamino acids are useful for reducing the attachment of lauryl ether sulfate to human skin during washing (column 5, lines 38-45). To support this use, the '514 patent cites earlier references that teach acyl glutamates as useful for alleviating skin irritations caused by other anionic surfactants, such as sodium lauryl sulfate (column 5, lines 53-60). Furthermore, the '514 patent provides detailed testing methods for determining SLS adsorption on skin; however, no testing methods are provided for determining cleansing effect of the combined surfactants. In other words, cleansing synergism is not a factor in the choice of co-surfactant according to the '514 patent. Rather, a co-surfactant according to the '514 patent is chosen based upon its ability to reduce the attachment of sodium lauryl ether sulfate to human skin. This is clearly seen in claim 1 of the '514 patent, which recites a method for reducing the binding of sodium lauryl ether sulfate to skin comprising "selecting a co-surfactant which decreases or prevents binding." This reduced SLS skin binding effect is the thrust of the '514 patent, and any suggestion or motivation arising from the '514 patent can not be separated from this underlying goal.

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The Office would seek to broaden the '514 patent by alleging it suggests combining SLS with other surfactants to achieve a "synergistic cleansing effect" or to reduce SLS irritation by adding other cleansing surfactants. When the reference is properly considered as a whole, however, it is clear that the motivation a skilled artisan would take from the reference is to seek out other surfactants known to reduce binding of SLS to skin. To this end, nothing in the '514 patent would lead the skilled artisan to the XP abstracts. The '514 patent only teaches or suggests that a single type of surfactants, N-acyl amino acid surfactants, are useful for achieving the desired effect of reducing SLS skin binding. The '514 patent provides no teaching or suggestion of other types of surfactants, and particularly not olive oil carboxylates.

The Office argues the '514 patent and the XP abstracts address the same problem in the same field of endeavor. This is simply not the case with respect to the XP abstracts. Nothing in any of the XP abstracts can be pointed to as teaching or suggesting that the olive oil derivatives disclosed therein are effective at reducing skin binding of another surfactant, particularly SLS. Further, the XP abstracts do nothing more than disclose that surfactants can be prepared from olive oil derivatives. It is difficult to envision a problem in a field of endeavor that is addressed by the XP abstracts. The abstracts simply report the existence of a group of surfactants having low toxicity and irritancy.

Simply stated, Applicant respectfully submits there is no motivation to combine the disclosure of the '514 patent with the disclosure of the XP abstracts. The '514 patent discloses that a specific effect (reduced SLS skin binding) can be achieved by using specific surfactants (N-acyl amino acids) to form a specific composition having SLS and N-acyl amino acids as co-surfactants. As noted above, the '514 patent provides no further direction for the skilled artisan in seeking out other co-surfactants that may provide the same function of reducing SLS skin binding. The '514 patent certainly does not teach or suggest that olive oil derivatives may be useful for reducing SLS skin binding.

Furthermore, there are thousands of compounds known to be useful as surfactants. The XP abstracts merely classify olive oil derivatives among the other thousands of known surfactants. Neither the '514 patent nor the XP abstracts provide any disclosure that would motivate the skilled artisan to choose the olive oil derivatives of the XP abstracts for use in

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reducing SLS skin binding. The XP abstracts do not disclose this function, and the '514 patent does not lead the way to this conclusion.

Second, Applicant respectfully points out that the '514 patent clearly discloses that the combination of SLS with co-surfactants is known. As previously noted, it is known that SLS can cause skin irritation. However, the '514 patent notes that, because of the ready availability, the acceptable price, and the excellent washing properties, it is difficult to dispense with the use of SLS (column 2, lines 28-31). The patent goes on to state that it is known per se to use SLS in combination with other surfactants as washing-active agents (column 2, lines 40-41). Again, the '514 patent states that the person skilled in the art who would like to increase the skin compatibility of such preparations replaces some of the SLS with milder surfactants; however, this leads to undesirable effects, such as reduced foaming or cleansing performance (column 2, lines 42-47).

The '514 patent sought to remedy this shortcoming by preparing specific formulations using specific co-surfactants (N-acyl amino acids). It has already been shown above that these specific formulations disclosed by the '514 patent do not teach or suggest the presently claimed invention. Applicant respectfully points out, however, that this knowledge in the art for combining other milder co-surfactants with SLS, even when taken with the '514 patent or the XP abstracts, also does not teach or suggest the presently claimed invention.

Claim 1 recites a cosmetic or dermatological formulation, comprising sodium PEG-7 olive oil carboxylate in an active content of 0.01 to 1.8% by weight, based on the total weight of the formulation, and sodium lauryl ether sulfate. As pointed out in the '514 patent, the skilled artisan seeking to lessen the irritation of SLS on the skin would seek to replace SLS with another milder surfactant. Accordingly, the skilled artisan would seek to use the co-surfactant in amounts suitable as a replacement (*i.e.*, amounts approaching the original SLS concentration). This directly contrasts the present invention wherein sodium PEG-7 olive oil carboxylate is used in merely "catalytic" amounts.

Additionally, the XP abstracts themselves teach the use of the surfactants in amounts exceeding the "catalytic" amounts recited in the present invention. The XP 002233114 abstract specifically teaches that sodium PEG-7 olive oil carboxylate is a good natural alternative to be used in cosmetics and detergents (*i.e.*, a replacement surfactant). One of skill in the art would

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reasonably understand that using sodium PEG-7 olive oil carboxylate as a replacement would necessitate the use of much greater concentrations than those presently claimed. The XP 002233115 abstract merely teaches that sodium PEG-7 olive oil carboxylate is skin tolerant. Accordingly, one of skill in the art would find no teaching or suggestion of use in low concentrations, such as those presently claimed, and would rely on the motivation of the '514 patent for using the co-surfactant in the increased amounts expected when replacing SLS. The XP 002233116 abstract teaches toiletry compositions that are based on olive oil as a cleansing agent. One of skill in the art would clearly understand that using an olive oil product as the basis of a formulation would necessitate the use of much greater concentrations than presently claimed.

Furthermore, the Office has not provided any evidence that it would be within the common knowledge of the skilled artisan to use sodium PEG-7 olive oil carboxylate with SLS in the presently claimed concentrations. None of the XP abstracts provide any teaching as to the useful concentrations of the olive oil derivatives disclosed therein. The common knowledge in the art, according to the '514 patent, is to replace SLS with milder surfactants, suggesting the use of increased concentrations of the milder surfactant. Additionally, the Office has not cited even a single reference that teaches or suggests that PEG-7 olive oil carboxylate can be used in concentrations of 0.01 to 1.8% by weight to impart a skin irritation reducing effect.

In light of the above statements, it is clear that even if the skilled artisan relied upon the common knowledge in the art, as expressed in the '514 patent (*i.e.*, that one should replace SLS with a milder surfactant to reduce the skin irritation of SLS), it still would not lead the skilled artisan to the present invention. As noted above, the present invention recites a formulation comprising sodium PEG-7 olive oil carboxylate in an active content of 0.01 to 1.8% by weight, based on the total weight of the formulation, and sodium lauryl ether sulfate. Common knowledge in the art for making SLS milder and the disclosure of the XP abstracts would clearly be expected to lead to formulations including olive oil derivatives in much larger concentrations than the "catalytic" amounts used in the present invention.

Third, even if the cited references are properly combinable, which Applicant obviously does not admit, the combination still would not teach or suggest the presently claimed invention. As noted above, the present application is directed to a cosmetic or dermatological formulation

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comprising sodium PEG-7 olive oil carboxylate in an active content of 0.01 to 1.8% by weight, based on the total weight of the formulation, and sodium lauryl ether sulfate, and methods of use thereof. The combined references would not lead the skilled artisan to prepare such a formulation comprising an active content of PEG-7 olive oil carboxylate in the range noted above.

The Office argues that general differences in amounts, percentages, or concentrations will not support patentability of subject matter encompassed by the prior art unless evidence to the criticality has been established. Applicant has previously pointed out that the '514 patent can only be fairly viewed as teaching or suggesting N-acyl amino acids as co-surfactants for reducing skin binding effects of SLS and would not suggest the use of olive oil derivatives according to the present invention. Further, Applicant has also pointed out that the common knowledge in the art for replacing amounts of SLS with milder co-surfactants also would not motivate the skilled artisan to prepare the presently claimed formulations using SLS and only a "catalytic" amount of sodium PEG-7 olive oil carboxylate. The Office seeks a showing of criticality of concentrations; however, the Office has failed to recognize the surprising effects of the present invention that clearly make the presently claimed invention beyond the suggestion or motivation possibly provided by the cited references. In other words, even if the Office has made a case for prima facie obviousness (which Applicant obviously does not admit), the surprising effects of the present invention overcome such a showing.

To this end, Applicant respectfully directs the attention of the Office to Figure 1 of the present application, which illustrates the effectiveness of the formulations of the present invention for reducing SLS absorption. The figure shows absorption values for 10% SLS alone and 10% SLS combined with sodium PEG-7 olive oil carboxylate at concentrations of 0.7%, 1%, 2%, and 4%. As the figure illustrates, SLS skin absorption is significantly reduced through use of only 0.7% sodium PEG-7 olive oil carboxylate. Furthermore, the reduction in skin absorption was not statistically significantly reduced by increasing the amount of sodium PEG-7 olive oil carboxylate up to 4%. This is clearly surprising, and even contrary, to what would be expected in light of the previously known art.

As noted in the '514 patent, common knowledge in the art is to reduce irritation of SLS on the skin by replacing amounts of the SLS with other, milder, surfactants. According to such

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knowledge, it is clearly expected that using more of the milder surfactant would increase the mildness of the formulation. One of skill in the art, based upon the knowledge asserted in the '514 patent, would not foresee the surprising effect of the present invention that less sodium PEG-7 olive oil carboxylate co-surfactant (0.7%) is, statistically speaking, as effective at increasing mildness as a greater amount (4%) of the co-surfactant. In fact, even if the skilled artisan was motivated to combine sodium PEG-7 olive oil carboxylates with SLS, knowledge in the art indicates the skilled artisan would use increasing amounts of the olive oil carboxylates to increase the mildness of the combination. Accordingly, Applicant respectfully submits the clearly surprising effects seen with the "catalytic" amounts of sodium PEG-7 olive oil carboxylate used according to the present invention overcomes any showing of obviousness the Office may assert.

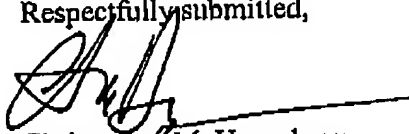
In light of the above statements, Applicant respectfully submits the present claims are not obvious over the cited art. First, there is not motivation to combine the references, as the '514 patent is clearly directed to specific combinations of specific surfactants for the specific purpose of reducing skin binding of SLS and would in no way lead the skilled artisan to the XP abstracts, which themselves in no way suggest usefulness in reducing SLS skin binding. Second, the motivation arising from the common knowledge in the art teaches away from the use of "catalytic" amounts of sodium PEG-7 olive oil carboxylates in combination with SLS, as the common knowledge is to replace SLS with milder surfactants, and this would necessarily require greater than "catalytic" amounts of the co-surfactant. Third, the present invention illustrates surprising effects arising from the use of merely "catalytic" amounts of sodium PEG-7 olive oil carboxylate that would not be expected by the skilled artisan in light of the state of the art, as pointed out in the '514 patent. Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection.

For the reasons provided above, Applicants respectfully submit all claims are in condition for allowance. Accordingly, Applicant respectfully requests that all rejections be withdrawn and a Notice of Allowance be issued in due course. If any minor informalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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11/28/05
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